

The Maryland Board of Pharmacy Public Minutes— June 10, 1998

President David Russo called the meeting to order at 8.45 A.M. In attendance were Commissioners Stanton Ades, Wayne Dyke, Dorothy Levi, W. Irving Lottier, Secretary, and George Voxakis, Board Counsel, Paul Ballard; Board staff, David Denoyer, Pam Owens, Norene Pease, Cheryl Cresic, and Tamarra Banks. Commissioners Barbara Jackson and William Johnson were excused and were absent from the meeting.

Guests present include:

Melvin Rubin, Pharmacist
Toni Connors, PEAC
Ray Love, University of Maryland, School of Pharmacy
Chris Mengler, Barr Laboratories
Gary Alexander, Rite Aid/Attorney
Chantel Ornsteing, Esq.
Robert Boerner, MPHA
Nathan Gruz, MPHA
Paula Farmer, DMPC
David B. Moore, MSHP
Lauren Baldwin, NACDS

Recusals - President Russo requested that any member of the Board with a conflict of interest relating to an item on the agenda should notify the Board at this time. There were no conflicts reported.

Minutes - A motion was made by Stanton Ades and seconded by Irving Lottier to approve the May Board minutes with a correction on page 5 the word met should be meet. The minutes were approved.

Executive Director's Report - Office secretary III, Cheryl Cresic was introduced. She will serve as secretary for the Board and for disciplinary and compliance matters. It was noted that the Board has accepted the resignation of Pamela Owens from the shared position of Legislative Officer. Ms. Owens has accepted a position with the Community and Public Health Administration coordinating legislative efforts for the Administration.

The Board is a preceptor site for the School of Pharmacy's Experiential Learning Program and will have five students from June through September. Ms. Pease introduced Stephen Kang who is serving in a internship capacity with the Board during the month of June. Ms. Pease and Mr. Denoyer will assign students to the following projects: researching the recent successes in other states with passage of collaborative practice legislation, researching recent action in other states regarding the use of pharmacy support staff (technicians) and update the Board's record of

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disciplinary charges and outcomes from 1995 until present to ensure consistency among common cases.

Ms. Pease informed those present that she had information regarding the sessions offered and the ten resolutions passed at the National Association of Boards of Pharmacy annual meeting that was held in May. In the interest of time she did not discuss the conference in detail but would make the information available to anyone interested in it.

Ms. Pease discussed the orientation of new Board members since their appointment to the Board appeared to be imminent. Irving Lottier and Stanton Ades volunteered to work with Ms. Pease to develop an orientation process since there will be four entirely new members assuming the two existing members who are eligible for reappointment are reappointed. Members reviewed a document developed by Ms. Pease, Irving Lottier and Dave Russo adding new committees to the current Board configuration. Ms. Levi felt that the Peer Review Committee should not include the duty of reviewing continuing education. Mr. Dyke agreed with Ms. Levi's recommendation and it was agreed that the Licensing Committee would continue to handle all functions associated with continuing education. The Board endorsed the new committee structure.

The National Association of Chain Drug Stores has offered to provide a stipend of \$1,000 to a representative from the Board to attend the 1998 Pharmacy Conference and Managed Care Forum. Ms. Pease inquired if this would present a conflict of interest for a representative of the Board. The Board instructed Ms. Pease to write a letter to the Ethics Commission inquiring if it would pose a conflict of interest to accept the stipend and if it would be a conflict of interest for a representative of the Board to attend the meeting and represent the Board.

Ms. Pease informed the Board that the Department had asked the Board to consider moving to an alternative building at Spring Grove Hospital Center, the Benjamin Rush Building. Ms. Pease and Ms. Banks have visited the building and both like it better than the Tawes Bland Bryand Building originally offered to the Board for consideration. The Dental, Physicians and Occupational Therapy Boards would move into the building and an adjoining structure named the Vocational Rehabilitation Building. A motion was made by Irving Lottier and seconded by Stanton Ades to approve the actions of Ms. Pease to continue discussions with the Department regarding a move to the Rush Building.

Board Counsel's Report - Board Counsel, Paul Ballard reported on the meeting of all health occupations Boards with the Office of the Assistant Attorney General to re-engineer the disciplinary process to ensure consistency across Boards and to improve methods for resolving cases in the most expeditious manner. Members of the Board requested receipt of the meeting report.

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Licensing Committee Report - The Licensing Committee met on May 27, 1998. Wayne Dyke reported that instead of a second letter being sent to renewal applicants who have not responded, the renewal letter being used presently could be revised to reflect the applicant's decision to renew or not. Mr. Dyke informed the Board that Hillary Soloff, Oral English Competency Vendor, has lowered her fees. It was also reported that the lab exam on June 22nd will consist of two wet lab sessions and on June 23rd three wet lab sessions. Proctors were asked to verify scheduling for the exams.

Mr. Dyke reported that there are 12 reciprocity candidates and a motion was made that all candidates be approved with the exception of the following who will be licensed when the Board receives their Oral English competency certificate: Maria Aloloyon, Talonna Iser, Christina Galiotos and Kara Tilisky. The 12 candidates are: Muntasir Hassan, Maria V. Aloloyon, Talonna C. Iser, Paumini Bhatt, Jenine C. Johnston, Chuhae Chon, Anisa M. Kratzer, Christina Galiotos, Kaumudi J. Patel, Kimberly Jefferson, Amy M. Traux and Kara A. Tilisky. The motion was approved. It was also stated that grading would be completed within a week after administration of the examination if possible.

Legislative Committee

No report at this time.

Strategic Planning Report

Ms. Pease reported that the next meeting is scheduled for June 24th at 8:00 am.

Regulation Update - Code of Conduct - Commissioner Ades and Ms. Owens discussed the proposed code of conduct. Ms. Owens explained that the Practice Committee had met several times and addressed dozens of written concerns, including a letter from Ms. Baroni at the NACDS. Specifically, the sections relating to therapeutic interchange in regulation .01, the patient privacy proposal in regulation .03, the duty to report regulation (.05) and the refusing to dispense (.08) regulations have been reconsidered and modified based on extensive deliberation and consideration of written comments. Mr. Ades suggested that the proposal is ready to be discussed and voted upon if the members so desire.

Gary Alexander, Rite Aid/Attorney and Lauren Baldwin, NACDS urged the Board not to vote at this time. Mr. Alexander expressed concerns with several sections of the proposal. The Board agreed to postpone the vote and agreed to allow interested parties to attend the July 8th Practice Committee Meeting to voice their concerns about the proposed Code.

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Electronic Transmission of Prescriptions - Board members discussed the proposed changes to COMAR 10.34.20, which is currently pending, but has been delayed due to reconsideration by the Practice Committee. Mr. Denoyer introduced comments from Ms. Baroni at the NACDS. Board members discussed regulation .03 and noted that the security inquiry required of the permit holder creates a potential liability for pharmacists and pharmacies. However, the discussion concluded with comments indicating that the burdens seem appropriate for the use of this new method to transmit prescriptions.

Another NACDS comment centered on the requirement for modem numbers in electronically transmitted prescriptions. Mr. Denoyer stated that the NACDS suggestion to remove references to modem numbers seems to be logical. Ms. Levi stated that some method of ensuring the facsimile and modem location is printed on the prescription would be useful. Mr. Ades commented that the modem number could be optional, but should not be required. Mr. Ades suggested that item .04E creates additional requirements that may not enhance the desired security function.

The issue of whether or not “hard copies” of electronic prescriptions are required was discussed. Mr. Denoyer stated further that .03E and .03F seem to be creating confusion, in part due to the order of the items, and the fact that .03E does not make it clear that all prescriptions need not be reduced to paper form.

Commissioner Ades motioned to delete 4E and pass with amendments and changes suggested, namely deleting all references to modem and facsimile numbers in regulation.04C and G, and to reorder .03 E and F, inserting the words “which is” before the “reduced to paper form” clause. Additionally, Mr. Ades suggested that the changes be reviewed by Mr. Russo and Lottier prior to submission to the Secretary. The motion to submit the proposal as amended was seconded by Dorothy Levi. The vote was in favor of the new proposal with amendments as discussed.

President Russo commented that the proposal will be printed and the finalized version will be sent to David Russo and George Voxakis, and Practice Committee members for guidance.

Chapter 19 Amendments - Parenteral/Sterile Enteral Compounding - Mr. Denoyer requested a motion to accept the amendments outlined in bold type. The amendments allow for the use of technology which is not strictly laminar flow, but that meets federal particulate guidelines. The proposal has been transmitted to members of the MSHP, and Mr. Denoyer anticipates no opposition. No comments were made. Stanton Ades motioned to approve bolded amendments and it was seconded by George Voxakis. The motion was approved.

Assisted Living Up-date - No discussions were held.

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PEAC Update - Toni Connor represented PEAC and reported that the Committee also had a concern with the Code of Conduct under section .05 Duty to Report. She asked that PEAC members and pharmacists attending alcoholics and/or narcotics anonymous meetings be exempt from reporting their peers who they know are in treatment and in recovery to the Board for review. She requested that the Board develop alternate language that remedies this situation.

PEAC Update - Stanton Ades

PEAC Representative's Report - Stanton Ades acknowledged Toni Conner representing PEAC. 501 3C approval next Fiscal Year needs to submit a budget and not have to go through University of Maryland.

Ms. Conner expressed concern over the language of Code of Conduct .05B. She also stated that a brief recap, a one page Annual Report will be distributed at the Ocean City MPHA meeting.

Audit Report - Ms. Banks reported that she and Mr. Ades have conducted an audit of the F.Y. 1998 PEAC contract and have found some irregularities for which they are seeking written explanation and documentation. Copies of the audit conducted May 18th were distributed to the Board, PEAC and University during the Board meeting. PEAC will be expected to respond to the items indicated in the audit report by June 26th and a final report; including PEAC's response will be submitted to the Board at the July Board meeting.

RFP Development - Tamarra Banks reported that PEAC; the rehabilitative committee recognized by the Board, was recently granted 501-3(C) status which establishes them as a small business. The Board voted at a previous meeting to competitively bid pharmacists rehabilitative services for FY 99 instead of continuing the noncompetitive agreement between the Board and the University of Maryland. The current terms for services will be modified to include specifics regarding reimbursement rates, utilizing professional accounting services, and documentation provisions. The contract with PEAC ends June 30, 1998. It was suggested that the agreement with the University for PEAC's services be extended until September 1st to allow for the completion of the competitive bid process. Board input is being solicited for the specifics of the new proposal. Dorothy Levi asked about the problem of reporting false positive results raised at the last meeting. PEAC is aware of the situation and will request better policy and procedures.

Pharmacy Practice Committee - Stanton Ade's June, 1998 meeting report stated that the discussion of the code of conduct and electronic transmission regulations composed the major portion of the practice committee meeting, and that the next meeting would be held on July 8 as planned. The meeting will include discussions with representatives from NACDS and MPHA regarding the Code of Conduct regulations.

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Budget Committee

Ms. Pease reported that she and Ms. Banks are working on the development of the F.Y. 2000 budget including initiatives. They will meet with Misters Dyke and Lottier to review the proposed budget before discussing it with the full Board.

The FY 2000 budget covers the period of July 1, 1999 to June 30, 2000. The issues in 2000 are under/over spent budget items, personnel changes (contractual positions, reclasses), new committees defined, specific committee initiatives, computer year 2000 problems and relocation issues. Revenue projections over the past two years will be reviewed and there will be discussion of the Health Care Access and Cost Commission's (HCACC) reported reduction in fees.

MMA Contract Extension - Tamarra Banks reported the agreement with MMA (Maryland Media Association) ends June 30, 1998. The public relations committee and the non-board oversight committee members will be asked to decide whether or not to renew the existing contract.

End of Life Task Force - Mr. Ades reported this is a Task Force formulated by the Office of the Attorney General to deal with end of life matters and pain management. This Task Force will respond to a request for proposal issued by the Robert Wood Johnson Foundation for grants of \$600,000 per site to develop public policy addressing end of life issues. Benefits of this grant will include, removing barriers to appropriate care, developing practice standards for health professionals and increasing public understanding of the issues.

Questions for the Board

Past Inquiry

Alco Pharmaceuticals - Recommendations from Misters Ades, Denoyer and Freedman - The Board's policy which is consistent with COMAR regulation is to discourage the return of drugs from Assisted Living Residential settings, to pharmacies, unless the pharmacist is certain that there are no concerns related to the proper storage of previously dispensed medications. This policy is reflected in COMAR 10.34.15.

New Inquiries

PCS Service Based Networks - PCS drug management plan -This is a program designed for pharmacists to consult with diabetic patients on their illness and how to comply with recommended medications, exercise etc., in order to reduce emergency room and podiatrist visits. Mr Russo stated that he did not believe that the program required any change in law prior to implementation. Mr. Russo recommended adding the names of PCS representatives to the list for

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the Strategic Planning Committee.

Letter from AMA - The AMA recommends that the ASCP policies on the return of drugs from long-term care facilities be adopted. This would expand the ability of pharmacies to return drugs. It is recommended that a response be written, which explains that for nursing homes the Board allows returns of drugs as long as drugs are not stored in adverse conditions or illegally re-packaged. COMAR 10.34.23 should be attached with the response.

Harry B. Finke-Letter - Dr. Finke is concerned about the Board's position on support personnel duties, and with the position of the Division of Drug Control. David Denoyer will write a letter responding to Dr. Finke, focusing on what functions are safe for non-licensed technicians to perform. Commissioner Lottier and Mr. Denoyer will research a possible Newsletter item on this subject. It was noted that a task force on this matter is in the formative stages, and that several pharmacy students will be working on this issue over this summer.

Home Health Emergency Drugs Draft Concept Paper - Mr. Denoyer reported that Mr. Ades, Dr. Love and Mr. Ballard met with the Board of Nursing and representatives from Licensing and Certification and agreed in principle to draft regulations which would enable pharmacists to dispense emergency drug kits specified in the draft concept paper included in this month's packet. The new regulatory proposal would be reviewed by Practice Committee and/or reviewed by Paul Ballard. Mr. Denoyer will draft regulations and will review the draft with the Practice Committee. The Board members agreed that a notice of regulatory development should be filed.

CVS and Giant Food Pharmacies sharing Information - Senator Frosh is concerned about recent publications focusing on the use of prescription data, allegedly for marketing purposes. Norene Pease and David Russo will meet and draft a letter responding to Senator Frosh, educating him on what has been done and let him know we have been proactive in the field, consistently advocating written permission for the disclosure of patient data. The letter should offer to possibly meet with the Senator.

8. Informational

1. Recall Notice-Epipen
2. Ohio R.Ph.s Change Rx regimens
3. NACDS-Adult Immunization Conference
4. Registration Form - Pharmacy-Based Immunization Delivery
5. Compounding Symposium in Washington, D.C.
6. NACDS Pharmacy Conference & Managed Care Forum
7. Faxing Schedule II Prescriptions for Hospice Patients
8. Inadvertent substitution of Neoral and Sandimmune

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9. Voluntary withdrawal of Posicor

No discussion was held concerning Informational material.

9. Follow - Up Letters

Alco Pharmaceuticals, Allen Karpe, P.D., Rules-Return of Drugs

Mr. Denoyer stated that this letter restated the Board provision that drugs should not usually be returned.

Automated Dispensing - Ms. Levi noted that the Board had not yet responded to the request and invitation from Mr. Allen at Suburban Hospital. A letter will be sent to the new Director, Bona Benjamin, Pharmacy Manager, informing Ms. Benjamin that we are anticipating new Board Members on the Board and we will try to set up a meeting in August.

Respectfully Submitted,

W. Irving Lottier
Secretary